UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

September 12, 2006

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 63761-8, Sterilex Ultra Disinfectant Cleaner Solution; DP Barcode: 331172

From: Tajah L. Blackburn, Ph.D., Microbiologist
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9/12/06

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Applicant: Sterilex Corporation
11409 Cronhill Drive, Suite L
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Formulations from Label

Active Ingredient(s)	% by wt.
n-Alkyl (C_{12} 68%, C_{14} 32%)	
Dimethylethylbenzyl ammonium chloride	3.00%
n-Alkyl (C_{14} 60%, C_{16} 30%, C_{12} 5%, C_{18} 5%)	
Dimethylbenzyl ammonium chloride	3.00%
Hydrogen peroxide	6.30%
Inert Ingredients	87.70%
Total	100.00%

I BACKGROUND

The product, Sterilex Ultra Disinfectant Cleaner solution, is a registered component of a two-part product. The product must be used with Sterilex Ultra Activator Solution. Per the comment section of the Bean Sheet (registrant letter is not included in the Data Package), the applicant has requested to amend the current registration to add claims for effectiveness against Avian Influenza A (H3N2). The product may be used in laboratories, veterinary/animal facilities, transportation terminals, hotels, factories, office buildings, barber shops, salons, homes, cafeterias, institutions, schools, athletic facilities, locker rooms, dressing rooms, and restrooms. The submitted efficacy study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

The data package contained one study (MRID No. 468701-01), Statement of No Data Confidentiality Claims for one study, and the proposed label.

II USE DIRECTIONS

The product is designed for use in disinfecting hard, non-porous surfaces such as floors, walls, countertops, stovetops, sinks, appliances, plastic cutting boards, chopping blocks, coolers, food processing equipment, kennel runs, cages, waterers, feeders, dressing plants, loading equipment, cabinets, highchairs, garbage cans, display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, bathtubs, sinks, urinals. The label indicates that the product may be used on surfaces composed of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, hard fiberglass, plastic (polystyrene, polypropylene), enameled surfaces, finished/sealed and painted woodwork, finished floors, Formica, and vinyl upholstery. Directions on the proposed label provided the following information regarding preparation and use of the product as a

> Disinfectant: Sterilex Ultra disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution, is a one-step hospital disinfectant at 12.8 fl. oz. (each solution 1 & solution 2) per gallon of water (1:1:10).
>
> Virucide against Avian Influenza A: Sterilex Ultra disinfectant Cleaner Solution 1, when mixed with Sterilex Ultra Activator Solution is effective against Avian Influenza A on hard, inanimate surfaces in one step at 2 fl. oz. (each, Solution 1 & Solution 2) per gallon of water (1:1:64), with a 5 minute contact time in the presence of 400 ppm hard water and organic soil.

III AGENCY STANDRDS FOR PROPOSED CLAIMS

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To

simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

Label Requirements for Farm Premise Disinfectants (DIS/TSS-18)

The following label directions are required for farm premise disinfectants to permit their classification as non-food use products:

1. Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acids, and pine oils)
2. Remove all animals and feed from premise, vehicles, and enclosures.
3. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
7. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
8. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Label Requirements for Poultry House Disinfectants (DIS/TSS-19)

The following label directions are required for poultry house disinfectants to permit their classification as non-food products:

1. Remove all poultry and feeds from premises, trucks, coops, and crates.
2. Remove all litter droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap and detergent rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. MRID No. 468701-01, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" Against Avian Influenza A (H3N2) Virus (Avian Reassortant). Study conducted by Kelleen Gutzmann, MS. Study completion date—April 27, 2006. Project Number #A03805.

This study was conducted against Avian Influenza virus, type A (Avian Reassortant; Strain A/Washington/897/80 X A/Mallard/New York/6750/78) (ATCC VR-2072) using Rhesus monkey Kidney cells. Two lots (Lot #ST2-19-1 and Lot #ST2-19-2) of the product, Sterilex Ultra Disinfectant Cleaner Solution 1 with the activator Sterilex Ultra Cleaner Solution 2 (Lot# 5C020) were tested according to ATS Labs Protocol No. SLX01121905.AFLU.1. The product was prepared by mixing 1.0 ml of Solution 1 and 1.0 ml of Solution 2 in 640 ml of 400 ppm AOAC Synthetic Hard Water. Films of the virus were prepared by spreading 0.2 ml of virus over the bottoms of three separate glass Petri dishes. The virus films were dried for 20 minutes at 18.5°C at 38% humidity. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Virus films were exposed to 2.0 ml of the diluted product for five minutes at room temperature (18.5°C). Following the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and the virus-test substance mixture was immediately passed through a Sephadex column utilizing the syringe plunger in order to detoxify the mixture. The filtrate (10^{-1}) was then titered by 10-fold serial dilution and assayed for infectivity. RMK cells in multi-well culture dishes were inoculated with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO2, and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus counts, cytotoxicity, and viability.

V RESULTS

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 ml)
			Lot #ST2-19-1 + Sterilex Ultra Cleanser Solution-2 (Lot# 5C020)	Lot #ST2-19-2 + Sterilex Ultra Cleanser Solution-2 (Lot #5C020)	
468701-01	Avian Influenza A (H3N2)	10^{-1} to 10^{-7}	No cytotoxicity	No cytotoxicity	$10^{5.5}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 468701-01) support the use of the product Sterilex Ultra Disinfectant Cleaner Solution 1 (1.0 ml), when combined with Sterilex Ultra Cleaner Solution 2 (1.0 ml) and diluted in 64.0 ml of 400 ppm hard water for a contact time of 5 minutes in the presence of 5% fetal bovine serum when used against Avian Influenza (H3N2: Avian Reassortant) on hard, non-porous surfaces at room temperature (18.5°C).

Note—The registrant needs to verify that Sterilex Ultra Cleaner Solution 2 (used in the efficacy study) is identical to Sterilex Ultra Activator Solution (on the proposed label).

VII RECOMMENDATIONS/LABEL COMMENTS

1. The proposed label claims are acceptable regarding the use of the product, Sterilex Ultra Disinfectant Cleaner 1, when used with Sterilex Ultra Cleaner Solution 2 (if identical to Sterilex Ultra Activator Solution) on hard, non-porous surfaces at 2 fl. oz. per gallon of 400 ppm hard water for a contact time of 5 minutes in the presence of organic soil. Data provided by the applicant support this claim.

2. Avian Influenza claims should be limited to areas located on farm and/or poultry premises, only. Veterinary facilities, animal care facilities, zoos, pet shops, and kennels, should not be included in the list of use sites for which avian influenza contamination is a concern. The Agency is not currently accepting these use sites for this product. Refer to DIS/TSS-18 and -19 (included in this review) for further guidance.

3. On page 1 of the proposed label, the specific strain of Avian Influenza should be included.

4. On page 2 of the proposed label, under the Directions for Use section, namely the portion labeled Disinfection and Spoilage Organisms, a contact time should be included for each section, as is consistent with submitted and accepted efficacy data.

5. The proposed label indicates that the product may be used on fiberglass surfaces (see page 3 of the proposed label). Fiberglass is a porous surface. This general

reference to fiberglass surfaces should be deleted. Specific fiberglass surfaces (e.g., fiberglass bathtubs) may be listed on the product label.

6. The proposed label indicates that the product may be used on picnic tables (see page 3 of the proposed label). Expand this use site to include "non-wooden" picnic tables.

7. The proposed label indicates that the product may be used on "sidewalls and floors" (see page 3 of the proposed label). More information should be provided regarding the types and components of these surfaces (i.e., some sidewalls and floors are porous) to ensure that they are indeed non-porous.

8. The proposed label indicates that the product may be used on refrigerators and other refrigeration units. Expand this label verbiage to include the exterior of these appliances.